



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

[Faint, illegible text in a box, possibly a title or description of the invention.]

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09 451,641

Applicant(s)

Gao et al.

Examiner

Susan Tran

Group Art Unit

1615



X Responsive to communication(s) filed on Oct 30, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 1-83

is/are pending in the application.

Of the above, claim(s) 51-75

is/are withdrawn from consideration.

Claim(s)

is/are allowed.

X Claim(s) 1-50 and 77-80

is/are rejected.

X Claim(s) 76 and 81-83

is/are objected to.

Claims

are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on is/are objected to by the Examiner.

X The proposed drawing correction, filed on Nov 30, 1999, is X approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number)

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received:

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s) 3

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application Control Number: 09 451,641

Art Unit: 1615

DETAILED ACTION

Information Disclosure Statement filed 03/28/00, Extension of Time filed 04/06/00 and 10/30/00, Declaration 04/06/00, and Election filed 10/30/00.

Election/Restriction

Applicant's election without traverse of Group I (claims 1-50, and 76-83) in Paper No. 7 is acknowledged.

Claims 51-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1615

Claims 77-80 are indefinite in the use of the phrase "such that" in line 2. The phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-50 are rejected under 35 U.S.C. 102(a and b) as being anticipated by U.S.

Prescribing Information for CELEBREX (Searle-Pfizer-Pharmacia).

Searle-Pfizer-Pharmacia discloses a Celebrex[®] capsule comprising 100 mg and 200 mg of celecoxib, croscarmellose sodium, magnesium stearate, povidone, and sodium lauryl sulfate (page 1 through page 2). Table 1 discloses the peak plasma levels of celecoxib occur approximately 3 hours after oral administration.

The examiner notes that the cited reference does not include the date of publication. The examiner will reconsider the above rejection provided that the applicants submit the date of the reference.

Art Unit: 1615

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black EP 0 863 134 ("134").

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprising active ingredient in admixture with excipients, i.e. diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent present in an amount of 10 to 250 mg, and carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be administered once or twice a day, and will provide effective $T_{1/2}$ over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

The examiner notes that the reference is silent as to the teaching of celecoxib. However, it is the position of the examiner that celecoxib is one of the selective Cox-2 inhibitor and thus, it would have been prima facie obvious for one of the ordinary skill in this art to, by routine

Art Unit: 1615

experimentation determine suitable Cox-2 inhibitor to treat cyclooxygenase-2 mediated diseases without any adverse side effect to the gastrointestinal.

4. Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Prescribing Information for CELEBREX (Searle-Pfizer-Pharmacia), in view of Black ('134).

Searle-Pfizer-Pharmacia is relied upon for the reasons stated above. The reference differs from applicants claimed invention by not specifically teaching the percent by weight of the excipients.

Black teaches a compound useful as a COX-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprising active ingredient in admixture with excipients, i.e. diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent present in an amount of 10 to 250 mg, and carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be administered once or twice a day, and will provide effective relief over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients used in a tablet. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to prepare the CELEBREX® composition using the percent amount of excipients in view of the teaching of Black to obtain the claimed invention, because the reference teaches the advantageous results accrue in the use of celecoxib.

Art Unit: 1615

Claims 76, and 81-83 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "T. C. Page". The signature is fluid and cursive, with a long horizontal stroke extending to the right.